UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDSUTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-CV-12257-PB: Judge Patti B. Saris
THIS DOCUMENT RELATES TO ALL ACTIONS	

MEMORANDUM OF WARRICK PHARMACEUTICALS CORPORATION IN SUPPORT OF ITS MOTION TO DISMISS

Warrick Pharmaceuticals Corporation ("Warrick") moves to dismiss Plaintiffs' Master Consolidated Class Action Complaint ("Complaint") pursuant to Fed. R. Civ. P. 12(b)(1), 12(b)(6), 9(b), [and 17(a)]. In this memorandum, Warrick asserts three arguments in support of its motion to dismiss not addressed in the Defendants' Consolidated Memorandum: All Plaintiffs lack standing against Warrick, Class 2 Plaintiffs have not stated a claim against Warrick, and the allegations against Warrick do not satisfy Rule 9(b).

I. Plaintiffs Have Not Alleged Standing Against Warrick

The Complaint does not allege facts sufficient to establish Article III standing against Warrick. To allege standing, Plaintiffs "must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Allen v. Wright*, 46 U.S. 737, 751 (1984). As argued more fully in the Memorandum of Bayer Corporation In Support of Its Individual Motion to Dismiss (incorporated herein by reference), a Plaintiff must allege it paid for a Warrick-manufactured drug to have standing. Except Twin Cities Bakery Workers Health and Welfare Fund ("TCBW"), no Plaintiff alleges payment for any Warrick-manufactured drug. *See* Compl. ¶¶ 13-26; 28-49. For this reason alone, all Plaintiffs except TCBW lack standing.

TCBW also lacks standing. TCBW alleges that it "paid charges" for one Covered Drug manufactured by Warrick – albuterol sulfate. *See* Compl. ¶25. These payments of charges allegedly

208

consisted of Medicare co-payments incurred by TCBW members and paid by TCBW. *See* Compl. ¶ 149. But, TCBW does not allege that these Medicare co-payments were based on albuterol sulfate AWPs. The distinction between charges and AWP is critical. Under 42 C.F.R. § 405.517(b), Medicare co-payments are 20% of the lesser of the provider's actual charges or 95%-of-AWP. Accordingly, under the allegations of the Complaint, TCBW's alleged overpayments are not "traceable" to Warrick, but rather to the providers who set the charges that TCBW paid. Thus, because all Plaintiffs lack standing to pursue their claims against Warrick, all claims against Warrick should be dismissed.

II. Class 2 Plaintiffs Do Not Allege Any Claim Against Warrick

The claims of Class 2 Plaintiffs -- Counts III, IV, V(as to Class 2 Plaintiffs), and VII -- should all be dismissed as against Warrick because Warrick manufactures generic pharmaceutical products, and the Class 2 claims made in Counts III-V and VII are made only with respect to branded products. *See* Compl. ¶333 (defining Class 2 to include all third-party payors that contracted with a PBM or other intermediary to provide participants a brand name drug manufactured by a defendant).

Counts III and IV of the Complaint allege RICO violations on behalf of Class 2 Plaintiffs against certain defendant drug manufacturers, apparently including Warrick, related to alleged unlawful conduct associated with brand name prescription drugs. *See* Compl. ¶¶397-423 (Count III); ¶¶ 424-450 (Count IV). Count V alleges violations of eleven state Consumer Protection Statutes, apparently on behalf of both Class 1 and Class 2 Plaintiffs, and Count VII seeks declaratory and other relief from certain defendants for unlawful conduct associated with brand name drugs. See Compl. ¶¶ 451-457 (Count V); ¶¶ 462-465 (Count VII). However, Warrick, as Plaintiffs admit in the Complaint, manufactures only generic drugs. See id. ¶ 122 ("Warrick manufactures generic pharmaceuticals"). Counts III, IV, and VII, made on behalf of only Class 2 Plaintiffs, explicitly exclude other defendant drug manufacturers who Plaintiffs allege manufacture only generic drugs, but for some reason Plaintiffs have still included

Warrick in these counts.[1] Because Class 2 Plaintiffs allege unlawful conduct only with respect to brand name prescription drugs, and because Plaintiffs have not alleged (nor could they allege) that Warrick manufactures brand name drugs, Warrick should be dismissed from Counts III, IV, V(as to Class 2 Plaintiffs), and VII of the Complaint.

III. The Allegations Against Warrick Do Not Satisfy Rule 9(b)

A. Plaintiffs Fail to Allege Fraud With Particularity.

Rule 9(b) applies to both the RICO and the state law consumer fraud counts because they are based on "averments of fraud."[2] RICO claims based on mail or wire fraud also require specificity in the pleading of the predicate mailings or wirings. Conclusory allegations, like those in the Complaint, that generically refer to a defendant's "extensive use of wires and mails" are not enough. *See Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 (1st Cir. 1991) (dismissing RICO claims for failure to allege supporting conclusory allegation that racketeering activity consisted of mail and wire fraud).

Just as Plaintiffs do not allege the time, place, or content of any Warrick communications, Plaintiffs also do not allege the "who, what, where and how" of Warrick's alleged fraud. See *Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997); *see also United States of America ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001). Plaintiffs do not allege even basic facts such as what Warrick said to Medicare, industry publications, or plaintiffs; when those statements were made; who made them; who relied on them and how they relied on them. For this reason, Plaintiffs' claims against Warrick must be dismissed.

---

[1] As explained in detail in the Memorandum of Law in Support of Motion to Strike Paragraphs 155-56 of the Master Complaint and Motion for a More Definite Statement filed concurrently herewith by Warrick and Schering-Plough Corporation ("Schering"), plaintiffs improperly have created something called the "Schering-Plough Group" and have made allegations against the "Group" rather than against either Schering or Warrick individually. This does not change the fact that plaintiffs have pled, correctly, that Warrick manufactures only generic drugs and that Counts III and IV apply to only brand name manufacturers. In fact, as described in detail in Schering's Memorandum in Support of the Motion to Dismiss, the Master Complaint completely fails to make any allegations against Schering individually.

[2] *See Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996) (Rule 9(b) applies to RICO); *Varney v. R.J. Reynolds Tobacco Co.*, 118 F. Supp. 2d 63, 72 (D. Mass. 2000) (dismissing consumer fraud act claim for failure to comply with Rule 9(b)).

Furthermore, Plaintiffs do not explain how or why it is fraudulent for an AWP to exceed actual acquisition cost. Both the federal government and the media understood AWP to be a benchmark price that was significantly higher than the price at which drugs were sold. *See* Cons. Mem. at 3-20. Plaintiffs do not allege how it is fraudulent for an AWP to exceed acquisition cost when Congress and HCFA repeatedly called AWP a "sticker price" that is not related to sales price. Plaintiffs do not allege that Warrick, or any other Defendant ever represented that the AWPs for their drugs was anything other than a benchmark price. These omissions are fatal, as Rule 9(b) requires a plaintiff to specify why an alleged fraudulent statement is false. *See Suna*, 107 F.3d at 68 (requiring plaintiff to explain why statements were fraudulent); *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993) (same).

The facts here resemble *United States ex rel. Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347 (D. Mass. 1999), in which the Court dismissed a Medicare fraud case under Rule 9(b) because the plaintiff failed to allege why or how the defendant's price representations were fraudulent. The defendant in *Gublo* was a medical device supplier accused of defrauding Medicare by submitting reimbursement claims that set forth charges for devices that did not reflect the discounts routinely given to non-governmental payors and purchasers. *See id.* at 354-55. Dismissing the Complaint under Rule 9(b), the court noted that the plaintiff "fail[ed] to point to any section of the [Medicare] regulations that requires [defendant] to factor discounts given to private insurers into the determination of its 'actual charges' for government billing purposes." *Id.* Here also, plaintiffs allege that Medicare and others overpaid for drugs because defendants allegedly reported AWPs that substantially exceed sales price in the non-Medicare market. As in *Gublo*, Plaintiffs cannot identify any Medicare statute of regulation that requires AWPs to be based on actual sales prices. To the contrary, Congress purposefully selected AWP as the Medicare benchmark, knowing that it frequently exceeded acquisition cost.

B. TCBW Fails to Plead Fraud With Particularity.

TCBW's bare allegation that it paid for a Warrick-manufactured drug does not provide sufficient facts to satisfy 9(b), *see* Compl. ¶ 25, because it does not account for the way Medicare calculates payment for generic drugs, including albuterol sulfate. Under 42 C.F.R. § 405.517(c), no single manufacturer's published AWP determines Medicare payment for a generic drug. Rather, Medicare payment is based on the lesser of (i) the provider's charge, (ii) 95% of the median AWP for all generic forms of the albuterol sulfate, or (iii) 95% of the lowest AWP for a brand name form of the drug. Under this regulatory framework, a single manufacturer cannot determine the Medicare reimbursement for albuterol sulfate. TCBW must explain how Warrick's allegedly inflated AWP resulted in injury to TCBW. Without any explanation of how that causal connection is to be made, TCBW's claims must be dismissed.

In addition, to the extent that Plaintiffs do allege Warrick "marketed the spread," this regulatory framework also renders nonsensical those allegations.[3] *See* Compl. ¶318. The Medicare allowable amount for all forms of a generic drug is the same. See 42 C.F.R. § 405.517(c). Warrick cannot, therefore, "market the spread" by "manipulating" its AWP to gain competitive advantage over another company. For these reasons, the Complaint's allegations against Warrick do not satisfy Rule 9(b), and the Complaint should be dismissed.

CONCLUSION

For the foregoing reasons, as well as those stated in the Joint Memorandum in Support of Defendants' Motions to Dismiss, Warrick requests that it be dismissed from the Master Consolidated Amended Class Action Complaint.

[3] As noted earlier, throughout the body of the Complaint, Plaintiffs make allegations only against the "Schering-Plough Group," not against either Warrick or Schering-Plough Corporation

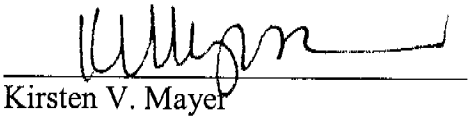
Respectfully Submitted,

Brien T. O'Connor (BBO#546767)
John T. Montgomery (BBO#352220)
Kirsten V. Mayer (BBO#641567)
David C. Potter (BBO#644610)
Ropes & Gray
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000

Dated: November 4, 2002

CERTIFICATE OF SERVICE

I hereby certify that on November 4, 2002, I caused a true and correct copy of the Memorandum of Warrick Pharmaceuticals Corporation in Support of its Motion to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.



Kirsten V. Mayer